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510(K) Summary
ChromoCheck™ Protein C

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023990

Submitters Name & Address:	Precision BioLogic Incorporated 900 Windmill Road, Suite 100 Dartmouth, Nova Scotia B3B 1P7 Canada
Contact Name:	Stephen L. Duff – Director of New Business Development Phone: 902-468-6422 ext. 224 Fax: 902-468-6421 Email: sduff@precisionbiologic.com
Preparation Date:	November 18, 2002
Device Name & Classification:	ChromoCheck™ Protein C Common Name: Protein C chromogenic assay Classification Name: Test, Quantitative factor deficiency Regulatory Class II, 81 GGP
Predicate Device:	Chromogenix AB/Instrumentation Laboratory Taljegardsgatan 3 S-431 53 Molndal Sweden, SW
Device Description:	ChromoCheck™ Protein is a chromogenic assay consisting of a synthetic substrate and Protein C Activator.
Device Intended Use:	ChromoCheck™ Protein C is intended for use as a chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Comparison to Predicate Device:

Parameter	ChromoCheck™ Protein C	Coamatic Protein C
Intended Use	Test, Quantitative factor deficiency	Test, Quantitative factor deficiency
Analytes	Protein C activity	Protein C activity
Component Reagent Matrices	**Reagent 1**: Chromogenic substrate in distilled water matrix **Reagent 2**: Protein C activator in a distilled water matrix	**Reagent 1**: Chromogenic substrate in distilled water matrix **Reagent 2**: Protein C activator in a distilled water matrix
Format	Lyophilized	Lyophilized
Packaging	4 x Protein C Activator (0.65 IU) 4 x Substrate (4 mg) (Reconstituted volume – **2.5** mL)	2 x Protein C Activator (1.2 IU) 2 x Substrate S-2366 (6 mg) (Reconstituted volume – **7.2** mL)
	4 x Protein C Activator (0.65 IU) 4 x Substrate (4 mg) (Reconstituted volume – **5.0** mL)	

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that **ChromoCheck™ PC** is substantially equivalent to **Coamatic Protein C** (K922201), manufactured by Chromogenix AB, and currently marketed in the United States by Instrumentation Laboratory. This opinion is based on the following similarities:

1. Both products are intended for use in the quantitative determination of Protein C activity in citrated human plasma
2. Both devices are based on synthetic chromogenic substrates
3. Both devices contain a synthetic chromogenic substrate and Protein C Activator and are reconstituted with distilled water
4. Both devices present results as a % activity of Protein C
5. Both devices are offered in a lyophilized format

Correlation:

Two lot numbers of ChromoCheck™ Protein C were compared to Coamatic Protein C in a correlation study using a mix of 60 individual normal and pathological patient samples. The following correlation was achieved:

Correlation parameter	ChromoCheck Lot 1	ChromoCheck Lot 2
Y-intercept	0.632	-1.308
Slope	0.979	1.025
R^2	0.990	0.994

Conclusion: ChromoCheck™ Protein C is substantially equivalent to Coamatic Protein C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 2003

Mr. Stephen L. Duff
Director of New Business Development
Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia
Canada B3B 1P7

Re: k023990
Trade/Device Name: ChromoCheck™ Protein C
Regulation Number: 21 CFR § 864.7290
Regulation Name: Quantitative Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: February 26, 2003
Received: February 27, 2003

Dear Mr. Duff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K023990

Device Name: ChromoCheck™ Protein C

Indications for Use:

ChromoCheck™ Protein C is intended for use as an *in vitro* chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Sign-Off
of Clinical Laboratory Devices
Number K023990

✓ Prescription Use